K072871

OSSTEM Implant Co., Ltd.
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JAN 10 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: _____

1. Company and Correspondent making the submission:

	Company
Name	Osstem Implant Co., Ltd.
Address	#507-8 Geoje3-Dong Yeonje-GuBusan, 611-804, Korea
Phone	+82 51-850-2573
Fax	+82 51-861-4693
Contact	Sung Ryul, Kim

2. Device:
   Proprietary Name – MS system (Provisional)
   Common Name – Dental Implant
   Classification Name – Endosseous dental implant

3. Predicate Device:
   The Maximus™ OS Implant
   Dentatus Transitional Implants, MTI-MP™

4. Classifications Names & Citations:
   21CFR 872.3640, DZE, Endosseous dental implant, Class II

5. Description:
   The MS system (Provisional) is a dental implant system made of titanium metal intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

   It has a screw-formed one piece of fixture and abutment made of Titanium Alloy Ti-6AL-4V (ASTM F 136) ELI with diameter 1.8, 2.5mm and length 10, 13, 15mm. It has machined surface, and is supplied sterile.

It is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. It is substantially equivalent in design, function and intended use to the predicate devices.

6. Indication for use:
The MS system (Provisional) is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

7. Contra-indications:
MS system (Provisional) should not be used in cases where the remaining alveolar bone is too diminished to provide adequate width or height to surround the implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient available bone, poor bone quality, poor oral hygiene, heavy smoking, tobacco abuse, or medical conditions such as blood disorder or uncontrolled diabetes.

8. Review:
MS system (Provisional) has the same device characteristics as the predicate device. Material, design and use concept is similar.

MS system (Provisional) has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of MS system (Provisional) has been conducted. Appropriate safeguards have been incorporated in the design of MS system (Provisional).

9. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that MS system (Provisional) is safe and effective and substantially equivalent to predicate devices as described herein.

10. Osstem Implant Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2008

Osstem Implant Company, Limited
C/O Ms. Cathryn N. Cambria
Consultant
Cambria Regulatory Consulting, Incorporated
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K072871
Trade/Device Name: MS System (Provisional)
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 17 2007
Received: December 18, 2007

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

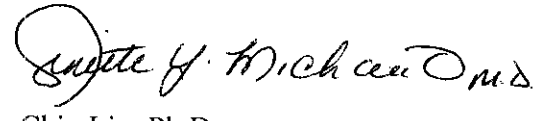
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 072871

Device Name: MS system (Provisional)

Indication for use: The MS system (Provisional) is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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